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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,963	08/02/2001	Yoshihiro Chikami	401232/MIURA	2611
23548	7590	05/04/2004	EXAMINER	
LEYDIG VOIT & MAYER, LTD			GEORGE, KONATA M	
700 THIRTEENTH ST. NW				
SUITE 300			ART UNIT	PAPER NUMBER
WASHINGTON, DC 20005-3960			1616	

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/857,963	CHIKAMI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Konata M. George	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_\_.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-16 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-16 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>6</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

Claims 1-16 are pending in this application.

### ***Information Disclosure Statement***

1. The information disclosure statement (IDS) submitted on September 26, 2001 and February 19, 2003 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

### ***Drawings***

2. Examiner acknowledges that this application contains drawings. The drawings will be sent to the draftsperson for review and a decision will be rendered in the next office action.

### ***Claim Language***

3. Claims 1-16 are directed to a product by process claims. However, it is not clearly defined in the preamble of the claims. Applicant is advised to reword the preamble to recite either "A process of preparing coated biologically active particles..." or "A method of making coated biologically active particles..."

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 1-16 are rejected under 35 U.S.C. 102(a) as being anticipated by Tadao et al. (JP 10-118557).

Tadao et al. discloses a method of coating particles comprising a resin solution. The resin in the resin solution is thermoplastic and can be polyolefin [0014]. Paragraph [0015] teaches that inorganic filler represented by talc may be employed in the resin solution. Paragraph [0020] teach the particles to be coated are fertilizers, pesticide, microbicide, etc. Paragraph [0025] teaches a coating solution for a fertilizer wherein the solvent used in the coating liquid is toluene. It is the position of the examiner that by allowing the solvent to dry or evaporate removes the solvent from the core and thus the ppm would be less than 500 and in fact it can be 0.

5. Claims 1-5 and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Ambegaonkar et al. (US 4,891,223).

Ambegaonkar et al. teaches a controlled release delivery coating for bioactive substances. The formulation comprises a bioactive material core (i.e. pesticide, fertilizer, etc.) and two distinct coatings (col. 5, lines 23-35). Column 6, lines 50-63 teach the two coatings and their compositions. The outer coating consists of a polymer, polymer blends, resins, etc. While Ambegaonkar et al. does not disclose a volatile substance incorporated into the particles, it is the position of the examiner that since it is claimed that the concentration of the substance is 500 ppm or less, then if the particles does not contain the substance then it is considered less than 500 ppm.

6. Claims 1-5, 8-10 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Murayama et al. (US 4,851,027).

Murayama et al. discloses a coated fertilizer composition. Column 2, lines 40-54 discloses coating a solid fertilizer with a coating material comprising a resin. It is also taught that the coating material is a mixture of the resin, a film forming aid, etc. The resin as described in column 4, lines 40-68 are copolymers selected from several species of monomers of which olefin compounds are one. While Murayama et al. does not disclose a volatile substance incorporated into the particles, it is the position of the examiner that since it is claimed that the concentration of the substance is 500 ppm or less, then if the particles does not contain the substance then it is considered less than 500 ppm.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 1-4, 11 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Momberger et al. (US 5,955,104).

Momberger et al. discloses a pharmaceutical dosage form comprising an inert core, an active ingredient core, and a coating over the active ingredient layer (abstract and col. 2, lines 42-65). Column 4, lines 7-12 teach that volatile solvents such as ethanol, isopropanol, acetone, etc. can be used to apply the active over the inert core. Column 4, lines 13-20 teaches how the active layer is applied to the core. It is taught that after the application of the active layer a period of time can be allotted to allow the drying/evaporation of the solvent between layers. It is the position of the examiner that by allowing the solvent to dry or evaporate removes the solvent from the core and thus the ppm would be less than 500 and in fact it can be 0.

### ***Conclusion***

8. Claims 1-16 are rejected.

### ***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is

(571) 272-0613. The examiner can normally be reached from 8AM to 5:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at (571) 272-0602. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Konata M. George  
Patent Examiner  
Art Unit 1616